

## **902 KAR 20:400. Limited services clinics.**

RELATES TO: KRS 311.550(12), 311.860, 314.011(7), 29 C.F.R. 1910.1030, 45 C.F.R. 160, 164

STATUTORY AUTHORITY: KRS 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes licensure requirements for the operation of and services provided by limited services clinics.

Section 1. Definitions. (1) "Advanced practice registered nurse" is defined by KRS 314.011(7).

(2) "Cabinet" means the Cabinet for Health and Family Services.

(3) "Clinic" means a limited services clinic.

(4) "Physician" is defined by KRS 311.550(12).

Section 2. Licensure Application and Fee. (1) An applicant for licensure as a limited services clinic shall complete and submit to the Office of the Inspector General an Application for License to Operate a Health Facility or Service, pursuant to 902 KAR 20:008, Section 2(1)(f).

(2) The initial and annual fee for licensure as a limited services clinic shall be \$500.

Section 3. Scope of Operations and Services. (1) A limited services clinic shall:

(a) Be located in a nonmobile facility;

(b) Not have an extension or satellite;

(c) Except for the provision of health care services at an off-site location for the purpose of community vaccination or a health screening drive, assure that limited health services as described in subsection (3) of this section are provided to patients exclusively at the facility's location;

(d) Not provide services to a child younger than twenty-four (24) months of age; and

(e) Provide appropriate referrals for each patient who requires care and treatment that is beyond the scope of services provided by the clinic.

(2) If a clinic is located within a retail location, the clinic shall have policies and procedures which ensure that patients are informed that they are not required to purchase any recommended or prescribed item from the host retail location.

(3) Health care services provided by a clinic shall:

(a) Be limited to conditions that may be safely and efficiently treated on an outpatient basis; and

(b) Include assessment, diagnosis, treatment, or counseling concerning any of the following:

1. Upper respiratory infection;

2. Sinus infection;

3. Allergy symptoms;

4. Acute bronchitis;

5. Ear infection or ear ache;

6. Ear wax removal;

7. Sore throat;

8. Influenza, excluding pregnant women;

9. Cold;

10. Coughs;
11. Laryngitis;
12. Breathing treatments with nebulizer;
13. Nausea, diarrhea, and vomiting;
14. Fever, excluding patients who have had a fever longer than seventy-two (72) hours;
15. Early Lyme Disease;
16. Pink eye or sty;
17. Skin infection or skin condition, which may include insect bites, rashes, ringworm, poison oak or ivy, scabies, hives, or impetigo;
18. Minor burn;
19. Skin tag removal;
20. Head lice;
21. Scalp rash;
22. Swimmer's itch;
23. Athlete's foot;
24. Cold sores;
25. Shingles;
26. Tick or insect bites;
27. Abrasions;
28. Minor cut closure with liquid skin adhesive;
29. Splinter removal;
30. Sprains or strains;
31. Urinary infection for females only, age twelve (12) to sixty-five (65);
32. Patient education and counseling;
33. Sports physical;
34. Camp physical;
35. School physical;
36. Vaccinations for patients age eleven (11) and older;
37. Influenza vaccinations for patients age twenty-four (24) months and older;
38. Pre-employment health screening;
39. Tobacco cessation therapy;
40. Skin wart removal;
41. Tuberculosis testing;
42. Hypertension;
43. Hypercholesterolemia;
44. Congestive heart failure;
45. Asthma;
46. Chronic obstructive airways disease;
47. Diabetes mellitus; or
48. Hyper- or hypothyroidism.

(4) If a clinic provides chronic disease management services for hypertension, hypercholesterolemia, congestive heart failure, asthma, chronic obstructive airways disease, diabetes mellitus, or hyper- or hypothyroidism, the clinic shall:

(a) Act as a source of patient and caregiver education by providing counseling and information regarding:

1. Disease management;
2. Medication use and compliance;
3. Lifestyle modification;
4. Community resources; and

5. Any other issue as appropriate and within the scope of training and knowledge of the practitioner;

(b) Within one (1) business day:

1. Schedule a follow-up appointment for the patient, upon the patient's consent, with a primary care provider; or

2. Assist the patient with scheduling a follow-up appointment, if requested, with a primary care provider, which may include providing the patient with a list of primary care practices in the area that are accepting new patients;

(c) Ask the patient whether he or she gives consent for the clinic's practitioner to contact the patient's specialist or primary care provider to discuss the patient's treatment plan a minimum of once every twelve (12) months;

(d) Send a visit-specific report by facsimile or electronically to the patient's specialist or primary care provider, if available and with patient consent, no later than one (1) business day after the patient receives chronic disease management services from the clinic;

(e) Participate in the Kentucky Health Information Exchange (KHIE) pursuant to the requirements of 900 KAR 9:010; and

(f) Make arrangements for the delivery of the services the clinic provides during the hours it is not open, at least through an answering service referring patients to another provider of the same services that is as geographically close as possible and is open at those hours. A clinic may provide a taped message that directs patients to a toll-free number which enables the patient to speak directly with a practitioner. These arrangements shall be reflected in a written policy which shall be made available to the clinic's patients.

(5) This administrative regulation shall not limit a clinic's ability to:

(a) Order a laboratory test specific to a patient's presenting symptoms for a condition described in subsection (3) of this section. Only CLIA (Clinical Laboratory Improvement Amendments) waived testing may be performed on-site in a limited services clinic;

(b) Provide treatment, testing, screening, or monitoring for a patient pursuant to a patient's designated plan of care or order from a practitioner other than the practitioner who is staffing the limited services clinic;

(c) Provide episodic treatment for an acute exacerbation of a chronic condition that does not rise to the level of an emergency;

(d) Write a prescription for a patient's maintenance medication. The clinic shall document its effort to contact the prescriber; or

(e) Make an initial diagnosis of a patient's chronic illness and refer to an appropriate practitioner, where treatment, including the prescribing of medication:

1. Shall not exceed thirty (30) days unless further directed by the patient's appropriate practitioner; or

2. May continue beyond thirty (30) days for a patient who does not have a primary care provider or specialist if:

a. The patient provides written consent at each subsequent visit for continued treatment of his or her chronic disease while seeking a primary care or specialist provider; and

b. The clinic documents its efforts to assist the patient in accessing a primary care provider or specialist, which shall include:

(i) Providing the patient with a list of primary care providers in the area; and

(ii) Assisting the patient, upon consent, with scheduling an appointment with a primary care provider or specialist who is accepting new patients.

(6) If a patient fails to provide written consent as required by subsection (5)(e)2.a. of this section for continued treatment of his or her chronic disease after the clinic made the initial diagnosis, the clinic shall cease treatment, including prescribing of medication for the patient's

chronic disease.

(7)(a) If the cabinet receives a request from an individual for modification of any part of this administrative regulation, the cabinet shall appoint and convene an advisory committee within sixty (60) calendar days of receiving the request.

(b) The committee shall include at least one (1) representative from the:

1. Kentucky Hospital Association;
2. Kentucky Medical Association;
3. Convenient Care Association;
4. Kentucky Board of Nursing;
5. Kentucky Coalition of Nurse Practitioners and Nurse Midwives; and
6. Kentucky Academy of Family Physicians.

(c) The committee shall:

1. Review each request for modification within sixty (60) calendar days of receiving the request as required by paragraph (a) of this subsection; and
2. Make recommendations to the cabinet regarding approval or denial of the request for modification within forty-five (45) calendar days after the date the committee convenes to review the request.

(d) If the cabinet accepts all or any part of the committee's recommendation to modify this administrative regulation, the cabinet shall file an amendment to this administrative regulation within forty-five (45) days of the committee's recommendation.

#### Section 4. Administration and Operation. (1) Licensee.

(a) A licensee shall be an entity or individual whose clinic:

1. Provides limited health care services as described by Section 3(3) of this administrative regulation; and
2. Is legally responsible for the clinic and for compliance with all federal, state, and local laws and administrative regulations pertaining to the operation of the clinic.

(b) A licensee shall establish written policies for the administration and operation of the clinic.

(c) A licensee shall establish lines of authority and designate a clinic director who shall:

1. Be employed by or under contract with the licensee;
2. Be principally responsible for the daily operation of the clinic; and
3. Maintain oversight of the clinical activities and administrative functions in the clinic.

(2) Policies.

(a) Administrative policies. A clinic shall have written administrative policies which shall:

1. Be maintained on the premises of the clinic or maintained in an electronic format, available for copying to a disk or printing at the clinic;
2. Be subject to review, inspection, and copying by the cabinet; and
3. Cover all aspects of the clinic's operation, including:
  - a. A description of organizational structure, staffing, and allocation of responsibility and accountability, including the clinical director's responsibilities described in subsection (3)(f) of this section if the clinic provides chronic disease management services;
  - b. Clinical practice guidelines for diagnosing and treating patients in each of the service categories provided by the clinic to ensure the proper identification of patients whose needs are beyond the clinic's scope of services;
  - c. Guidelines for referring an individual whose needs exceed the clinic's services;
  - d. Policies and procedures for determining if physician consultation is required;
  - e. Policies and procedures for the guidance and control of personnel performances;
  - f. Procedures to be followed if the clinic performs any functions related to the storage, han-

dling, and administration of drugs and biologicals; and

g. Procedures for the submission of a patient's written or verbal grievance to the clinic. The grievance process shall specify time frames for review of the grievance and the provision of a response.

(b) Patient rights policies.

1. A clinic shall:

a. Adopt written policies regarding the rights and responsibilities of patients;

b. Display publicly at the clinic a copy of its written policy regarding the rights and responsibilities of patients; and

c. Provide a copy of the clinic's patients' rights policies upon request by an individual who seeks services there.

2. A clinic's patient rights policies shall assure that each patient is:

a. Informed of services available at the clinic;

b. Provided a right to information regarding the charge to the patient for each service offered by the clinic and whether the clinic accepts payment for the proposed services from third-party payors, including insurance, Medicare, or Medicaid;

c. Informed of his or her medical condition, unless medically contraindicated as documented in his or her medical record;

d. Notified of all relevant treatment or maintenance courses of action and given the opportunity to participate in the clinical decision-making process;

e. Informed that he or she may voice a grievance or recommend changes in policies and services;

f. Assured confidential treatment of his or her records and is afforded the opportunity to approve or refuse the release of those records to an individual not involved in his or her care, except as required by third-party payment contract or otherwise permitted by applicable law; and

g. Treated with consideration, respect, and full recognition of his or her dignity and individuality, including privacy in treatment and in the care of his or her personal health needs.

(3) Personnel.

(a)1. During a clinic's operating hours, the clinic shall have present at least one (1) advanced practice registered nurse, physician, or physician assistant approved for off-site supervision according to KRS 311.860.

2. The clinic shall employ additional staff or ancillary personnel as needed to ensure the safe and efficient delivery of services provided by the clinic.

(b)1. Clinic personnel shall attend in-service training programs relating to their respective job duties. These training programs shall include:

a. Thorough job orientation for new personnel; and

b. Regular in-service training programs, emphasizing competence and professionalism necessary for effective health care.

2. A written document describing the training programs completed by all clinic employees shall be maintained on the premises of the clinic.

(c) During a clinic's hours of operation, at least one (1) health care professional shall be at the clinic who has:

1. Training in basic cardiac life support for health care providers; and

2. Training in the treatment of anaphylactic reaction.

(d) A clinic or its management entity shall maintain a written job description for each position that shall be reviewed and revised as necessary.

(e) A clinic or its management entity shall maintain current personnel records for each employee. An employee's personnel record shall include the following:

1. Employee's name, address, and social security number;

2. Evidence that the health care professional has a valid license or other valid credential required for the professional to be able to practice;
3. Record of training and experience; and
4. Record of performance evaluations.

(f) If a clinic provides chronic disease management services for hypertension, hypercholesterolemia, congestive heart failure, asthma, chronic obstructive airways disease, diabetes mellitus, or hyper- or hypothyroidism, the clinic shall designate a Kentucky-licensed physician or advanced practice registered nurse to serve as the clinic's clinical director. The physician or advanced practice registered nurse may serve as the clinical director for more than one (1) clinic and shall:

1. Assist the clinic in developing policies, procedures, and treatment plan recommendations to assist in quality patient care;
2. Participate in quality assurance and improvement activities, including monthly electronic chart reviews completed by the clinical director or a Kentucky-licensed physician in conjunction with a practitioner from each clinic in which at least ten (10) percent of the clinic's patient records shall be randomly selected for review, and of this ten (10) percent, at least fifty (50) percent of the records reviewed shall be randomly drawn from the clinic's chronic disease management patient records, not to exceed fifty (50) chart reviews;
3. Maintain documentation of the quality assurance and improvement activities required by subparagraph 2 of this paragraph;
4. Promptly respond to clinical questions from a practitioner who renders clinical services in the clinic;
5. Ensure that the clinic for which he or she serves as clinical director is:
  - a. Certified by the Convenient Care Association; or
  - b. Accredited by:
    - (i) The National Committee for Quality Assurance;
    - (ii) The Accreditation Association for Ambulatory Health Care;
    - (iii) The Utilization Review Accreditation Committee;
    - (iv) The Joint Commission; or
    - (v) Other nationally recognized accrediting organization with comparative standards; and
6. Provide in-service and educational sessions to the clinic's health care practitioners or assure that the clinic's practitioners have completed continuing education in compliance with the requirements of his or her professional license.

(g)1. A clinic or its management entity shall maintain the materials required by this subsection and make the materials immediately available to the cabinet or its duly appointed representative upon request.

2. The materials shall be subject to review, inspection, and copying by the cabinet or its duly appointed representative.

(4) Medical records.

(a) A clinic shall maintain medical records that contain the following:

1. Medical history relevant to services provided by the clinic;
2. Description of each medical visit or contact, including a description of the:
  - a. Condition or reason for the visit or contact;
  - b. Assessment;
  - c. Diagnosis;
  - d. Services provided;
  - e. Medications and treatments prescribed; and
  - f. Disposition made;
3. Reports of physical examinations, laboratory, and other test findings; and

4. Documentation of referrals made, including the reason for the referral and to whom the patient was referred.

(b) A clinic shall maintain confidentiality of patient records at all times pursuant to and in accordance with federal, state and local laws and administrative regulations including the privacy standard promulgated pursuant to Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. 160 and 164.

(c) A clinic shall:

1. Establish systematic procedures to assist in continuity of care if the patient moves to another source of care;

2. Transfer medical records or an abstract upon request, subject to required releases and authorizations; and

3. Have a specific location designated for the storage and maintenance of the clinic's medical records or maintain scanned copies of the original medical records in an electronic format or maintain electronic health records, available for copying to a disk or printing at the clinic.

(d) A licensee shall safeguard the clinic's medical records and their content against loss, defacement, and tampering.

(e) Medical records shall be maintained by the clinic for a period of six (6) years following the last treatment, assessment, or visit made by the patient, or three (3) years after the patient reaches age eighteen (18), whichever is longer.

(5) Quality assurance program. A clinic shall:

(a) Have a written quality assurance program that:

1. Includes effective mechanisms for reviewing and evaluating patient care; and

2. Provides for appropriate responses to findings; and

(b) Maintain a copy of the written quality assurance plan on the premises of the clinic.

Section 5. Provision of Services. (1) Posting requirements. A clinic shall post the following information on the door patients use to enter the clinic or prominently near the clinic's entrance:

(a) The clinic's hours of operation;

(b) The clinic's name; and

(c) A list of services provided by the clinic, accompanied by a statement which advises that the clinic is not equipped to provide emergency treatment for life threatening conditions.

(2) Visits. A clinic shall:

(a) Provide each patient with a copy of the visit summary sheet at the conclusion of the visit; and

(b) Upon request by the patient, send a copy of the visit summary sheet or visit-specific medical record, including documentation of any vaccinations administered by the clinic, by facsimile or electronically to the patient's primary care practitioner at no charge to the patient, or provide a paper copy of the visit summary sheet to the patient to deliver to the patient's primary care practitioner.

(3) Referral. If an individual seeks or is in need of care and treatment in excess of services beyond the scope of limited services offered by the clinic, the clinic:

(a) Shall immediately advise the individual that he or she should seek services elsewhere; and

(b) May make a referral on behalf of the individual.

(4) Equipment. Equipment used for direct patient care shall comply with the following:

(a) The licensee shall establish and follow a written preventive maintenance program to ensure that equipment is operative and properly calibrated;

(b) All personnel engaged in the operation of the equipment shall have adequate training

and be currently licensed, registered, or certified in accordance with applicable state statutes and administrative regulations; and

(c) A written plan shall be developed and maintained to provide for training of personnel in the safe and proper usage of the equipment.

Section 6. Compliance with Applicable Statutes and Regulations. Each health care professional who provides services at a clinic shall act at all times in compliance with:

(1) Obligations or requirements associated with his or her respective professional license or credential; and

(2) Applicable federal, state, and local laws and administrative regulations including the privacy standard promulgated pursuant to Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. 160 and 164.

Section 7. Physical and Sanitary Environment. (1) Accessibility. A clinic shall meet requirements for making buildings and facilities accessible to and usable by the physically handicapped pursuant to federal, state, and local laws.

(2) Fire safety. A clinic shall be approved by the state Fire Marshal's office before licensure is granted by the cabinet.

(3) Physical location and overall environment.

(a) A clinic shall have at least one (1) exam room.

(b) The condition of the physical location and the overall environment shall be maintained in such a manner that the safety and well-being of patients, personnel, and visitors are assured.

(c) The premises shall have a waiting room or seating for waiting patients near the entrance to the clinic.

(d) The clinic shall develop written infection control policies that are consistent with Centers for Disease Control guidelines, available at [www.cdc.gov/ncidod/dhqp/guidelines.html](http://www.cdc.gov/ncidod/dhqp/guidelines.html), and shall include:

1. Prevention of disease transmission to and from patients, visitors, and employees, including:

a. Universal blood and body fluid precautions;

b. Precautions against airborne transmittal of infections; and

c. Work restrictions for employees with infectious diseases; and

2. Cleaning, disinfection, and sterilization methods used for equipment and the environment.

(e) The clinic shall provide in-service education programs on the cause, effect, transmission, prevention, and elimination of infections.

(f) The clinic's facility, equipment, and surroundings shall be kept in a condition of good repair, neat, clean, free from accumulation of dirt, rubbish, and foul, stale, or musty odors.

(g) Hazardous cleaning solutions, compounds, and substances shall be:

1. Labeled;

2. Stored in closed metal containers;

3. Kept separate from other cleaning materials; and

4. Kept in a locked storage area apart from the exam room.

(h) The clinic shall be kept free from insects and rodents, and their nesting places.

(i) Garbage and trash:

1. Shall be removed from the premises regularly; and

2. Containers shall be cleaned regularly as needed.

(j) A clinic shall establish and maintain a written policy for the handling and disposal of wastes, including any infectious, pathological, and contaminated wastes, which shall include the following:



1. Sharp wastes shall be segregated from other wastes and placed in puncture-resistant containers immediately after use;

2. A needle or other contaminated sharp shall not be recapped, purposely bent, broken, or otherwise manipulated by hand as a means of disposal, except as permitted by the Centers for Disease Control and the Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii);

3. A sharp waste container shall be incinerated on or off-site or rendered nonhazardous; and

4. Any nondisposable sharps shall be placed in a hard walled container for transport to a processing area for decontamination.

(k)1. Disposable waste shall be:

a. Placed in a suitable bag or closed container so as to prevent leakage or spillage; and

b. Handled, stored, and disposed of in such a way as to minimize direct exposure of personnel or patients to waste materials.

2. The clinic shall establish specific written policies regarding handling and disposal of waste material.

(l)1. A clinic shall provide a hand washing facility in each exam room with:

a. Hot and cold water and blade type operating handles;

b. Knee or foot controls; or

c. Motion activated technology.

2. A soap dispenser, disposable towels or electronic hand dryers, and a waste receptacle shall be provided at each hand washing sink.

(m)1. If a clinic is located on the premises of another entity and does not have toilet facilities located within the clinic, the clinic may share toilet facilities with the other entity.

2. A clinic that shares toilet facilities with another entity shall establish policies and procedures to protect the privacy and dignity of the patient.

(n) A licensee owned or operated incinerator used for the disposal of waste shall be in compliance with all applicable Kentucky statutes and administrative regulations. (36 Ky.R. 1572; Am. 2049-A; 37 Ky.R. 381; eff. 8-18-2010; TAm eff. 3-11-2011; 41 Ky.R. 1905; 2256; 42 Ky.R. 316; eff. 9-4-2015.)